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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
12/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,230	BOND ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2010*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,9-31,37-39,41-60 and 62-86* is/are pending in the application.

4a) Of the above claim(s) *67-80 and 82-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9-31,37-39,41-60,63-66 and 86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicant's amendments and remarks submitted September 22, 2010 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, 9-31, 35-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the viral infection with compound defined by formula I, wherein A is prydiyl, R1 is a phenyl or substituted phenyl, and R2 is COR3 wherein R3 is optionally substituted aryl, X is oxygen, does not reasonably provide enablement for other compounds encompassed by the general formula. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

3. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claim recites the employment of compounds defined by general formula I, wherein A is pyridyl for treatment of mammal infected with viruses of a Pneumovirinae sub family, particularly, SRV. The substituents R1 and R2 herein may be varied from simple alkyl groups, such as methyl, ethyl groups to aryl, heterocyclic groups. X may be oxygen, sulfur, or nitrogen. The general formula encompasses essentially unlimited number of compounds. It is speculated that the treatment is through the inhibition of the virus fusion processes (claim 30). The application discloses several hundreds of compounds, with few exception, all of them are those with R1 is a phenyl or substituted phenyl, R2 is COR3 wherein R3 is optionally substituted aryl, and X is oxygen. See, particularly, table 3. Most of the compounds are tested against RSV and the results are reported in table 7. It is noted that none of those compounds that not meet the limitation defined above, particularly, compounds 493-502 (table 3), are tested or reported. Therefore, the application lack sufficient working examples, guidance, or direction for supporting the scope of compounds defined by general formula I. Applicants fail to provide information allowing skilled artisan to ascertain the utility of these compounds against the viruses without undue experimentation. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on the employment of all the compounds defined by general formula I for treating the viral infections,

necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

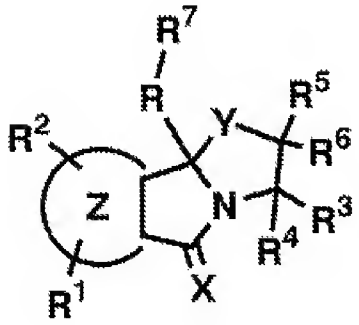
Claim Rejections 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 33, 38-39, 41-60, 62-66, 81 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bamba et al. (WO 02066479, IDS).

6. Bamba et al. teaches compounds as defined by the general formula:

7. 

8. wherein, Z is a fused aryl ring, such as pyridyl ring, X is O, S, or NR, R-R7 together, among other thing, may an alkyl, substituted alkyl, aryl, substituted aryl, etc. Y may be NR9, wherein R9 may be alkyl, aryl etc., R1, R2, R3 and R4 may be hydrogen, alkyl, aryl, etc. and the method of using the same for pharmaceutical composition. See, particularly, the abstract, and pages 5-11. Compounds with different substituents have been disclosed. See, particularly, pages 88-91.

9. Bamba et al. do not teach expressly example that is within the scope of the claimed limitation.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a compound within the scope of the claims herein, e.g., a compound as defined therein wherein Z is a substituted or unsubstituted pyridyl, X is oxygen, R and R7 together is a aryl, or substituted aryl; Y and NR9, wherein R9 is alkyl, or aryl substituted alkyl.

10. A person of ordinary skill in the art would have been motivated to make a compound within the scope of the claims herein because Bamba provides specific guidance and direction for making such compounds, and such compounds are known to be useful as therapeutical agents. Finally, one of the ordinary skill would have found it obvious to employ a stereoisomer of the known therapeutical compounds herein in the claimed composition since it is considered within the skill of the art to resolve the optical isomers of a known chiral compound, and each isomer is expected to be active in the absence of evidence to the contrary. See In re Anthony 162 USPQ 594; In re Adamson 125 USPQ 233.

Response to the Arguments

11. Applicants' amendments and remarks submitted September 22, 2010 have been fully considered. Rejections set forth in the prior office action, but are not reiterated herein are withdrawn in view of applicants' amendments and remarks. However, the amendments and remarks are not persuasive with respect to the rejection set forth above.

With respect to the rejection under 35 U.S.C. 112, applicants contend that the examiner have not shown his burden for proving the claims are not enabled This is inaccuracy. The

rejections provide the facts: The disclosed examples is not representative for the claimed scope, and the unpredictability of pharmaceutical art, and the lacks of support that the antiviral activity of the disclosed compounds would have been extrapolated to the full scope of the claimed compounds; and the law, particularly the Wands factors to be considered. Considering all the facts, and apply the facts to the law, the examiner made the conclusion that the claims are not enabled.

As to the compounds disclosed, it is noted that no antiviral activity has been disclosed for compounds 123, 337, 339, 342, 345, 350, 354, 356, 362, 374, 341, 343, 346, 348, 349, 373. See, tables 6-10. Compounds 351 and 371 are the only two compounds with reported antiviral activity. The two compounds characterized with R2 as COR3 with R3 is -CH2-Aryl. The two compounds only show very weak antiviral activity (TABLE 7). One of ordinary skill in the art would have no reasonable expectation that such compounds would be useful for treating RSV viral infection. For all other compounds the R3 is either aryl, heteroaryl, or substituted aryl heteroaryl.

12. With respect to the rejections over Bamba et al. (WO 02066479, IDS), applicant argue that Bamba reference are completely silent as to the treatment of RSV infection, and there is no motivation to make modification. This is not found persuasive. It is noted that, the compounds herein claimed encompass at least part of the compounds within the general formula disclosed in Bamba. Therefore, one of ordinary skill in the art, need no more motivation other than following the instruction provided by Bamba to make the compounds herein claimed. No modification is need. Further, In response to applicant's argument that the compound herein claimed is for treating HSV infection, which has not been disclosed or suggested by the reference, the fact that

applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1627